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10/553,626	08/30/2006	Masahiro Iwakura	040894-7330	7457

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MORGAN LEWIS & BOCKIUS LLP
1111 PENNSYLVANIA AVENUE NW
WASHINGTON, DC 20004

EXAMINER

LUNDGREN, JEFFREY S

ART UNIT	PAPER NUMBER
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1639

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/553,626	Applicant(s) IWAKURA ET AL.	
	Examiner JEFFREY S. LUNDGREN	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 1-4 and 8-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 5-7 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/30/06</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Status of the Claims

Applicants' election without traverse of Group II, claims 5-7, is acknowledged.

Claims 1-16 are pending in the instant application; claims 1-4 and 8-16 are withdrawn as being directed to a non-elected invention; claims 5-7 are the subject of the Office Action below.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file, namely, Japan Patent Application 2003-106450, filed on April 10, 2003.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on August 30, 2006, has been considered by the Examiner. The submission is in compliance with the provisions of 37 CFR § 1.97. Enclosed with this Office Action is a return copy of the Form PTO-1449 with the Examiner's initials and signature indicating those references that have been considered. Note: only the English language Abstracts from the cited documents have been considered.

Objection to the Claims

Claims 5-7 is objected for depending from a claim to a non-elected invention (*i.e.*, claim 1). Correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 5 is indefinite for reciting the phrase “a protein array” in the second line of the claim because this phrase already has antecedent basis. The second occurrence of the same claim limitation should use the language “the” or “said”. In the instant case, it is not clear if Applicants are referring to the first occurrence of “a protein array” or a second protein array. Correction is required.

Claim 5 is indefinite for reciting the phrase “*the* primary amino group of *the* polymer compound” because there is lack of proper antecedent basis. Applicants have not established that there is a polymer compound on the substrate, nor that this polymer compound has a primary amino group. Correction is required.

Claim 6 is indefinite for reciting the phrase “the above formula IV” because formula IV is found “below” the referenced term.

Claim 6 is indefinite for reciting the phrase “negatively charged *strongly*” because one of ordinary skill in the art could not reasonably determine the metes and bounds of this phrase. The term “strongly” is a relative term and does not allow one of skill in the art to distinguish which peptides are encompassed by the claim and the peptides that are excluded.

Claim 6 is indefinite for reciting the phrase “capable of acidifying the isoelectric point” because the metes and bounds of this limitation cannot reasonably be determined. This does not appear to be a term of art, nor defined or described in the specification with reasonable clarity. Correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 5-7 are anticipated by Zhou:

Claims 5-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Zhou et al., U.S. Patent Application Publication No. 2005/0048554 A1, published on March 3, 2005.

Claim 5 is directed towards a protein array comprising a protein represented by formula (I) aligned and immobilized on the substrate for a protein array according to claim 1 so that the carboxyl terminal of the protein main chain represented by formula (I) is immobilized by a peptide bond to the primary amino group of the polymer compound bound to the substrate:



wherein R₁ represents any amino acid sequence. Claim 6 is similar.

Zhou teaches platforms for easy and cost-effective fabrication of bio-microarrays are disclosed. In one embodiment, the platform contains a substrate having a surface coated with a film of alternating polycationic and polyanionic polymers. In another embodiment, the platform contains a substrate having a surface coated with a polyelectrolyte-silica sol-gel film. Also disclosed are bio-microarrays fabricated using the above platforms and methods of making the platforms and the microarrays (see Abstract).

Regarding the protein array of claim 5, Zhou teaches that protein arrays may be prepared:

“The use of **microarray-based technology** is growing rapidly and has had considerable impact in genomic and proteomic research [1-3]. One crucial component of microarray technology is the surface chemistry of the substrate. The chemistry should be suitable for spotting and **immobilizing a variety of biological active molecules** (DNA, **proteins** and cells) such that their biomolecular interactions may be evaluated. Therefore, strong emphasis is placed on developing innovative chemistries that provide high binding capacity, efficient hybridization, low background, good spot uniformity, and stability.”

Zhou, paragraph 0003 (emphasis added); see also paragraph 0008-0009.

Zhou teaches a number of polymer configurations and polymer components that may be used with the invention; included are poly(aspartic acid) as the polyanion, and poly-L-lysine of poly(allylamine) for the cation.

In Example 2, Zhou teaches protein microarrays within the scope of claims 5-7.

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Claims 5-7 are anticipated by Hubbell:

Claims 5-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Hubbell et al., U.S. Patent No. 6,884,628 B2, issued on April 26, 2005.

Hubbell teaches that multifunctional, polyionic copolymers with molecular architectures and properties optimized for specific applications are synthesized on/or applied to substrate surfaces for analytical and sensing purposes. The coatings are particularly useful for suppression of non-specific interaction, adsorption or attachment of molecular or ionic components present in an analyte solution. Chemical, biochemical or biological groups that are able to recognize, interact with and bind specifically to target molecules in the material containing the analyte to be detected can be coupled to, integrated into, or absorbed to the multifunctional copolymers. These multifunctional copolymer coatings are compatible with a variety of different established methods to detect, sense and quantify the target molecule in an analyte. The multifunctional copolymer coatings typically include brush copolymers based on a polycationic or polyanionic (jointly referred to herein as 'polyionic') backbone with side chains that control interaction with the environment, such as poly(ethylene glycol) or poly(ethylene oxide)-based side chains that decrease cellular adhesion, and analyte-specific side chains. They can be used to pattern the surfaces into non-adhesive and specifically adhesive areas by applications of known techniques such as microfluidic or contact printing techniques (see Abstract).

As in claim 5, Hubbell teaches the preparation of protein arrays:

“Two-dimensionally patterned surfaces are an important aspect of modern analytical and sensor devices such as biochips used today or in the future in DNA, RNA or *protein microarray and immunoassay technologies*. The technique allows the parallel detection of many different target molecules in one analyte of complex composition through specific surface functionalization and recognition site immobilization on a local scale. The three basic prerequisites are a surface technology that allows one to reproducibly fabricate geometrically patterned surfaces, a technique to immobilize recognition units on a localized scale and detection techniques that are compatible with the local scale of the individual assay.”

Hubbell, col. 26, lines 22-34 (emphasis added).

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Hubbell teaches a number of polyanion and polycation compositions for adsorbing the desired biomolecule to the surface (see Figures 1-2, and description thereof). As in claim 7, Hubbell teaches linkers, such as PEG linkers (col. 26, line 35-64).

Conclusions

No claim is allowable.

If Applicants should amend the claims, a complete and responsive reply will clearly identify where support can be found in the disclosure for each amendment. Applicants should point to the page and line numbers of the application corresponding to each amendment, and provide any statements that might help to identify support for the claimed invention (*e.g.*, if the amendment is not supported *in ipsiis verbis*, clarification on the record may be helpful). Should Applicants present new claims, Applicants should clearly identify where support can be found in the disclosure.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jeff Lundgren whose telephone number is 571-272-5541. The Examiner can normally be reached from 7:00 AM to 5:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher Low, can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jeffrey S. Lundgren/

Patent Examiner, Art Unit 1639